

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, *et al.*,

Plaintiffs,

Ex rel.,

JAMIE SIEGEL, M.D.,

Plaintiff-Relator,

v.

NOVO NORDISK, INC.,

Defendant.

CASE NO. D23-5459 BHS

ORDER

THIS MATTER is before the Court on plaintiffs Jamie Siegel and the State of Washington's¹ *Daubert* motion to exclude the opinion testimony of defendant Novo Nordisk's (NNI's) expert witness, Michael Tarantino, M.D. Dkt. 419.

¹ This Order refers to plaintiff relator Siegel and intervenor plaintiff Washington State together as "Washington" for clarity, ease of reference, and consistency. Siegel filed the motion.

1 Dr. Tarantino is a board-certified hematologist and is qualified as an expert in his
2 field of treating hemophilia patients. His Report, Dkt. 420-1, contends he has reviewed
3 65,000 pages of medical records of ten Washington Medicaid patients who used
4 NovoSeven for “severe Hemophilia A with inhibitors to FVIII,” including the off-label
5 use for prophylaxis and high doses, to evaluate whether their use of NovoSeven was
6 medically necessary, appropriate and accepted. He opines that the use of NovoSeven was
7 appropriate for eight of the patients; for the other two, he did not have enough data to
8 draw a conclusion. Dkt. 420-1.

9 Washington seeks to exclude Tarantino’s testimony under Federal Rule of
10 Evidence 702 and *Daubert*. Dkt. 419. It asserts that the issue in the case is not whether a
11 patient “appears to have been prescribed medically appropriate doses of NovoSeven,” but
12 instead whether Washington law governing reimbursement allows for payment. *Id.* at 1.
13 It argues that Tarantino has no expertise on this issue; he struggles to define the terms he
14 uses and does not tie them to any definition in a Washington law or regulation. It
15 contends he does not even mention the “compendia of drug information,” upon which
16 NNI’s summary judgment motion, Dkt. 386, in part relies.

17 Washington specifically contends that Tarantino’s Report “curiously” omits the
18 phrase “medically necessary” when opining that the use of NovoSeven was “appropriate”
19 and “safe.” *Id.* It contends that because Tarantino does not mention the “hierarchy of
20 evidence” required under Washington law to determine if a treatment is medically
21 necessary and thus reimbursable, and that his opinion does not address whether
22

1 Washington Medicaid regulations would or should have covered any “off label” uses of
2 NovoSeven under those regulations’ “medical necessity” standard. *Id.* at 2–5.

3 NNI responds that Washington’s theory of the case is that patients’ use of
4 NovoSeven was medically unnecessary and dangerous. It therefore asked Tarantino to
5 review the records and determine whether the NovoSeven prescriptions written for them
6 were medically necessary, appropriate and accepted, and whether the use was safe. Dkt.
7 443 at 4. It argues that Tarantino is qualified, and that based on his review of the medical
8 records, he opines that the prescriptions were medically necessary, appropriate, and
9 accepted, and that the use of NovoSeven was safe. *Id.* (citing Dkt. 420-1 at 6). It contends
10 these opinions are relevant, reliable, and admissible. *Id.* at 5.

11 A qualified expert may testify in the form of an opinion or otherwise only if the
12 proffered testimony is both relevant and reliable. Fed. R. Evid. 702; *Teradata Corp. v.*
13 *SAP SE*, 124 F.4th 555, 566 (9th Cir. 2024) (citing *Daubert v. Merrell Dow*
14 *Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)). Rule 702 and *Daubert* impose on the
15 district court a “gatekeeping” duty to ensure that opinion testimony is relevant and
16 reliable, and an expert’s opinion should be excluded if it does not have a reliable
17 foundation or if it is not based in the knowledge and experience of the relevant discipline.
18 *Sonneveldt v. Mazda Motor of Am., Inc.*, 2024 U.S. App. Lexis 32836, *3 (9th Cir. Oct.
19 21, 2024) (citing *Primiano v. Cook*, 598 F.3d 558, 564-65 (9th Cir. 2010)). “Expert
20 opinion testimony is relevant if the knowledge underlying it has a valid connection to the
21 pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in
22 the knowledge and experience of the relevant discipline.” *Surgical Instrument Serv. Co.*

1 | *v. Intuitive Surgical, Inc.*, 2024 U.S. Dist. Lexis 81690, *5 (N.D. Cal. March 31, 2024)
2 | (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 739 F.3d 960, 969 (9th Cir.
3 | 2013). When an expert meets the Rule 702 threshold the expert may testify, and the jury
4 | decides how much weight to give that testimony.” *Primiano*, 598 F.3d at 565.

5 | Washington emphasizes that, despite his assignment and his conclusion, most of
6 | Tarantino’s Report does not address the “medical necessity” of the prescriptions he
7 | reviewed and does not address the WAC 182-501-0165(6) “hierarchy of evidence”
8 | required to establish medical necessity for a NovoSeven prescription. Washington argues
9 | that Tarantino’s opinion might be relevant in a medical malpractice case, but it is not
10 | relevant to as to whether the NovoSeven prescriptions were reimbursable under
11 | Washington Medicaid regulations.

12 | As was the case with the *Daubert* motion to exclude the testimony of Dr. Manco-
13 | Johnson, this argument goes to the weight, not the admissibility of the opinion testimony.
14 | There is no dispute that Washington Medicaid paid for the use of NovoSeven during the
15 | relevant period—including after Dr. Jeffrey Thompson and the 2009 Hemophilia
16 | Working Group reviewed the use of NovoSeven for medical necessity, and authorized
17 | payment for its use. The Court has agreed that the loss of documents reflecting that
18 | review warrants an adverse inference instruction permitting the jury to infer that the
19 | documents would have shown that Washington Medicaid viewed the use of NovoSeven
20 | as medically necessary. Dkt. 480. Implicit in such an instruction is the possibility that a
21 | jury could find that while Tarantino and Manco-Johnson did not faithfully follow the
22 | hierarchy of evidence in concluding the use was medically necessary, there is similarly

1 no evidence that Dr. Thompson and the 2009 Hemophilia Working Group did so either,
2 though Washington Medicaid continued reimbursement for high dose and prophylactic
3 use of NovoSeven. Their opinions about this issue are relevant and admissible, and they
4 are subject to rigorous cross examination about WAC 182-501-0165(6)'s hierarchy of
5 evidence.

6 Tarantino's opinion testimony about the safety of NovoSeven in the cases he
7 reviewed is also reliable, and relevant, and admissible. *See* Dkt. 420-1 at 6, ¶ 11.

8 Tarantino will also be permitted opine as to why NovoSeven was used in the cases
9 he reviewed, to rebut Washington's contention that the NovoSeven prescriptions were the
10 result of illegal inducements. He will not be permitted to testify that the prescriptions
11 were *not* the result of the inducements, and Washington's motion is to this limited extent

12 **GRANTED.**

13 Tarantino is a qualified expert in his field, his review of the patients' medical
14 records used a reliable methodology based on sufficient facts and data and which will be
15 helpful to the jury on the "acceptable" and "safe" nature of the NovoSeven prescriptions
16 at issue. Tarantino's opinions are relevant, and they satisfy Rule 702's requirement they
17 assist the jury in understanding the evidence and determining facts in issue.

18 Washington's *Daubert* motion to exclude Dr. Tarantino's expert opinions, Dkt.
19 419, is otherwise **DENIED.**

20 **IT IS SO ORDERED.**

21 \\
22

1 Dated this 15th day of July, 2025.

2
3 

4 BENJAMIN H. SETTLE
5 United States District Judge
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22